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Calls Document "Smoking Gun" Proving that Politics Trumped Science at Agency

Washington, DC - Rep. Louise M. Slaughter (D-Fairport), Ranking Member of the House Rules Committee, today released the following statement in response to the public release of a GAO report documenting the reasons behind the FDA's recent refusal to approve the over-the-counter sale of Plan B emergency contraception.

"This report is the ‘smoking gun' which clearly demonstrates that the FDA based its decision on politics, and not science. A once trusted and highly respected agency, which based its decisions on the principles of science, has now been taken over by an extremist political agenda.

We commend GAO for conducting this difficult investigation with the utmost professionalism and integrity, and for shedding light on what can only be described as the intentional corruption of the established FDA approval process in the interests of a political agenda.

With this new information, we urge senior FDA officials to stop playing politics with the health and welfare of this country and immediately approve over-the-counter sales of Plan B.

I am also calling on my colleagues in Congress to hold hearings on this abuse of power and authority by the FDA to promote a blatantly political agenda."

BACKGROUND

GAO found that there were 4 unusual aspects to FDA's decision in May 2004 to not approve Barr Laboratories' application for over-the-counter sales of Plan B.

- 1. Directors did not sign non-approval letter - Directors of the Offices of Drug Evaluations III and V and the Director of the Office of New Drugs did not agree with the decision and did not sign the not-approvable letter.

- 2. Higher level than usual involvement in the decision - the review process for the Plan B OTC switch application was marked by FDA high-level management that was not typical for OTC switch applications. The acting Director of CDER (Center for Drug Evaluation and Research) signed non-approval letter. This is unusual. The Director has never signed an OTC letter before and he only signed a couple approval letters for prescription use of drugs.

- 3. Timeframe for decision is murky - FDA staff charged with reviewing the application claimed the decision for non-approval was announced at a reviewer staff meeting in January 2004, well before the review was finished. The original date for FDA to make a decision was set for Feb. 22 but then it was moved to May 2004, when Barr Labs agreed to provide more information on studies in adolescents.

- 4. Rationale for non-approval was unique - Never before were concerns about adolescents engaging in unsafe sexual behaviors considered when reviewing an application for approval - OTC and behind the counter. FDA said with their new focus for child health and safety, this consideration was now appropriate for them to examine. Despite their claims, all the studies that FDA staff reviewers examined showed that there were no increased poor behaviors among adolescents with easier access to EC. The studies also showed that adolescents could easily read the label and follow the recommended instructions.

Furthermore, FDA's joint advisory committee considered 23 OTC switch applications from 1994 to 2004. Plan B was the only 1 of those 23 that was not approved after the joint committee voted to recommend approval of the application. FDA considered a total of 67 drugs for OTC use from 1994-2004. Of which only 14 were not approved originally and later only 2 remained non-approved (including Plan B).

In late 2003, the FDA's own expert Advisory Panel voted overwhelmingly in favor (23-4) of allowing over-the-counter sales of Barr Laboratories' Plan B. The Advisory Panel and FDA's professional and scientific staff concluded that EC meets standard criteria for over-the-counter use: low-toxicity; no potential for overdose or addiction; no teratogenicity (is not harmful to an existing pregnancy); no need for medical screening; self-identification of the need; uniform dosage; and no significant drug interactions. Yet, 20 months later, the FDA still refuses to accept a sensible, safe solution to preventing unintended pregnancies.

Every day in America, thousands of women find themselves contending with unplanned pregnancies. If EC drugs like Plan B were readily available, they would help to prevent 1.7 million pregnancies and 800,000 abortions every year in the United States alone.

On August 26th, the Food and Drug Administration delayed its previously promised decision on whether to approve over-the-counter sales of Plan B. FDA's deadline for public comment on regulating over-the-counter sales of Plan B ended on November 1st. Yet, FDA continues to delay making a decision on Plan B.